## REMARKS

Claims 111-116, 129-134 and 143-148 have been canceled without prejudice as being drawn to non-elected subject matter. Applicants reserve the right to prosecute the subject matter of the canceled claims in related applications.

Applicants respectfully submit that the Examiner's withdrawal of Claims 149-154 was in error as these claims are not drawn to non-elected species. Applicants respectfully request that the Examiner consider these claims.

Claims 75, 109, 110, 119-125, 127, 128, 135-142 and 149-155 have been amended to remove non-elected subject matter or correct claim dependencies necessitated by cancellation of claims.

Claim 75 has been amended to correct a typographical error. Claims 75 and 155 have been amended to delete "at least" after "comprising", as redundant, since the term "comprising" means "consisting of at least". Claim 142 has been amended to correct claim dependency.

"Purified" has been inserted before "protein" in claims 109, 110, 119-122, 127, 135-138, 141 and 149-152 for proper antecedent basis.

Claims 109, 127 and 141 have been amended to clarify that which Applicants regard as the invention. Specifically, claims 109, 127 and 141 have been further amended to clarify that the binding portion of SEQ ID NO:51 is of at least 6 contiguous amino acids and mediates binding to HPT1. Support for this amendment can be found in the specification[1] at page 21, lines 6-7. Additionally, claim 109 has been amended to clarify that the active agent is a drug, imaging agent or antigen. Support for this amendment can be found in the specification, for example at page 40, lines 21-28. Claims 122, 138 and 152 have been amended to specify that the protein facilitates transport of the active agent through the gastrointestinal tissue. Support for this amendment can be found in the specification, for example at page 9, lines 16-21.

No new matter has been added by the present amendments.

After entry of the present amendment, claims 75, 109-110, 117-128, 135-142 and 149-155 will be pending in the present application.

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[1] Page and line references refer to the substitute specification filed in connection with the above-identified application on May 3, 2000.

## Claim Objections

Claim 75 was objected to because of the recitation "...a a...". Applicants have amended claim 75 to delete the second occurrence of "a". Accordingly, Applicants respectfully request withdrawal of the objection.

Claim 142 was objected to because it depends upon itself. Applicants have amended claim 142 to depend upon claim 141. Accordingly, Applicants respectfully request withdrawal of the objection.

## Rejections under 35 U.S.C. § 112, second paragraph

Claim 109 (and dependent claims 110 and 117-126) was rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The specific rejections are discussed below.

The Examiner alleges that the recitation of the terms "an active agent" and "an active agent being of value in the treatment of mammalian disease" in claim 109 is vague and indefinite and that the specification fails to disclose the metes and bounds of an "active agent". Applicants note that the claim have been amended to clarify that the "active agent" is an imaging agent, an antigen or a drug. This amendment sets forth the metes and bounds of an "active agent". Accordingly, Applicants submit that this rejection of claim 109 (and dependent claims 110 and 117-126) has been obviated.

The Examiner alleges that the recitation of the term "a binding portion thereof" in claim 109 renders the claims indefinite because the specification fails to disclose the metes and bounds of such a binding portion and fails to teach that to which the binding portion of the protein binds. Applicants point out that claim 109 has been amended to clarify that the binding portion is a portion of the protein of SEQ ID NO:51 of at least 6 contiguous amino acids that mediates binding to the HPT1 receptor. Further, Section 8.4 at pages 118-124 of the specification teaches how a portion of a gastrointestinal tract receptor binding peptide can be assayed to determined whether it is a "binding" portion. Accordingly, one of skill in the art can readily ascertain the metes and bounds of the portion of SEQ ID NO:51 recited in claim 109. Accordingly, Applicants submit that this rejection of claim 109 (and dependent claims 110 and 117-126) has been obviated.

For the above reasons, Applicants respectfully request withdrawal of these

rejections.

**Rejection under 35 U.S.C. § 112, first paragraph**

Claims 109, 110, 127 (and dependent claims 135-140), 128, 141 and 142 were rejected under 35 U.S.C. 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the binding portion is claimed (a) without any clear structural limitations and (b) without any functional limitations. As a preliminary matter, claims 110, 128 and 142 have been amended to delete recitation of "binding portion" making the rejections of these claims moot. As to claims 109, 127 (and dependent claims 135-140) and 141, Applicants respectfully disagree.

The legal standard for the written description requirement of 35 U.S.C. § 112, first paragraph, requires that an applicant "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555; 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). The Federal Circuit has recently stated that the description is deemed sufficient if it demonstrates to the skilled artisan that the applicant was in possession of the necessary common attributes of the members of the genus. *Regents of University of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied* 523 U.S. 1089 (1998).

The Examiner states that to fully describe a genus of a chemical compound, "applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these".

In the instant case, the Examiner contends that the specification makes no mention of "a binding portion thereof" in relation to SEQ ID NO: 51. In particular, the Examiner further contends that the sequence of SEQ ID NO:51 does not describe the structure of the binding portion nor can the binding portion be predicted based upon the disclosure since binding characteristics have not been described. Applicants respectfully submit that the specification, as filed, provides written description support for the claimed

subject matter.

As amended, claims 109, 127 and 141 recite, *inter alia*, a protein comprising the amino acid sequence of SEQ ID NO:51 or a portion thereof of at least 6 contiguous amino acids that mediates binding to HPT1. At least one species of the genus is fully described, *i.e.*, SEQ ID NO:51, such that a skilled artisan could predict the structure of other species encompassed by the claimed genus. The skilled artisan can examine SEQ ID NO:51 and select a region of at least 6 contiguous amino acids. Furthermore, common structural and functional characteristics are identified. Claims 109, 127 and 141 recite both a structural feature, *i.e.*, a protein comprising SEQ ID NO:51 or a portion thereof of at least 6 amino acids, and a functional activity, *i.e.*, mediation of binding to HPT1.

Given the disclosure of the instant application, and using methods well known in the art, the skilled artisan can readily make portions of SEQ ID NO:51 of at least 6 contiguous amino acids. The skilled artisan can also easily test such portions for their ability to mediate binding to HPT1, as taught in Section 8.4 of the specification at pages 118-124.

Thus, in light of the teachings of the specification, the levels of skill in the art and in light of the legal standard discussed *supra*, Applicants submit that the present disclosure provides a more than adequate written description of the claimed invention. As such, one skilled in the art would clearly understand that the inventors had possession of the invention at the time of filing the instant application.

In view of the foregoing, Applicant respectfully submits that the rejection of claims 109, 127 (and dependent claims 135-140) and 141 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is improper and request that the rejection be withdrawn.

## CONCLUSION

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the instant application. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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